Clinical Evaluation of the Latex Flocculation Test for Pregnancy

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• **Simultaneous pregnancy tests were run on duplicate specimens of urine by the Friedman method and the latex flocculation method on 329 patients. Clinical correlation was available in 245 of these patients. The latex test had a sensitivity of 77 per cent and a specificity of 92 per cent in the overall diagnosis of pregnancy. The Friedman test had corresponding values of 93 per cent and 97 per cent, respectively. Not until the second month of pregnancy did the latex test become sensitive enough for practical use.**

The Friedman test, which takes 48 hours, is more sensitive and specific for the determination of pregnancy than the in vitro latex flocculation test, the results of which are known in four hours.

SEVERAL LABORATORY TESTS have been utilized in the early diagnosis of pregnancy, most of them biologic tests with excellent sensitivity. Although these biologic procedures are reliable and easily performed, they have the disadvantages of the time required for the tests and the maintenance and care of laboratory animals.

The latex flocculation pregnancy test is based on an agglutination reaction in which anti-human chorionic gonadotropin antibody reacts in combination with the antigen polystyrene latex particles coated with human chorionic gonadotropin. In the pregnant patient, the urinary chorionic gonadotropin reacts with the anti-human chorionic gonadotropin antibodies, inhibiting the agglutination of the polystyrene latex particles. In the nonpregnant patient, on the other hand, the anti-human chorionic gonadotropin antibody remains free and can react with the polystyrene latex particles, with resultant agglutination.

The study reported in this communication represents an evaluation of an immunologic in vitro test and a biologic test for the diagnosis of pregnancy. The immunologic method consisted of a latex flocculation test[7] and the biologic test was the Schneider modification of the Friedman test.[6]

Materials and Methods

The study consisted of 329 specimens of urine from patients in whom pregnancy was suspected. The specimens were divided and the latex flocculation test was performed on one aliquot of urine according to the instructions outlined by the manufacturer. The Friedman test was run on the corresponding aliquot.

In this study, a correlation was made between the results of the latex test, the Friedman test and the clinical diagnosis. Clinical evaluation was available in 245 of the patients. A correlation was also made between results of these tests and the known length of the gestational period at the time the tests were done. The results are listed in Tables 1, 2 and 3.

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Submitted August 2, 1963.

Discussion

The level of human chorionic gonadotropin rises in the blood and urine during the first trimester, and it is during the latter half of this period that pregnancy tests are most reliable. Thereafter, the concentration declines rapidly although detectable levels are present until a week following parturition.[3]

The result of the latex test was compared with that of the Friedman test as outlined in Table 1. There were discrepancies in both the positive and negative results. To define the accuracy of each test, the results were correlated with the final clinical diagnosis as shown in Table 2. The Friedman test had a sensitivity of 93 per cent and a specificity of 97 per cent, whereas the latex test had corresponding values of 77 per cent and 92 per cent. Goldin[2] in his series observed a sensitivity of 94.9 per cent and a specificity of 96.7 per cent for the latex test. Henry and Little[4] found a specificity of about 95 per cent. In larger series by Eden and Black,[1] sensitivity of 92.2 per cent and specificity of 95.2 per cent were noted for the Friedman test and the corresponding values for the latex test were 72.8 and 87 per cent. Olson and Adducci[5] reported an accuracy of 88.24 per cent in early pregnancy with the latex test compared with 97.32 per cent for the rat ovarian hyperemia test. In their series, the accuracy of the latex test in late pregnancy was

TABLE 1.—*Comparison of the Latex Test with Friedman Test*

Reaction	Latex Test	Friedman Test
Positive	87	111
Negative	158	134

TABLE 2.—*Correlation of Latex Test, Friedman Test and Clinical Diagnosis*

	Patients Pregnant	Patients Not Pregnant
Latex negative, Friedman negative	7	120
Latex negative, Friedman positive	29	2
Latex positive, Friedman negative	2	5
Latex positive, Friedman positive	78	2

TABLE 3.—*Correlation of Latex Test, Friedman Test and Length of Gestation*

Gestational Period	Latex Test	Friedman Test
Less than 6 weeks	positive 5, negative 10	positive 14, negative 1
6 to 9 weeks	positive 42, negative 11	positive 51, negative 2
9 to 13 weeks	positive 16, negative 0	positive 16, negative 0
More than 13 weeks	positive 6, negative 1	positive 6, negative 1
Unknown	positive 10, negative 2	positive 12, negative 0

70.45 per cent as compared with 90.91 per cent for the rat hyperemia test.

Because of the poor sensitivity of the latex test, an attempt was made to determine when in the gestational period the latex test becomes significantly sensitive. The data on this study are summarized in Table 3.

It was apparent that the majority of the false negative results occurred within nine weeks from the onset of the last normal menstrual period and were more frequent with the latex test than the Friedman test. The latex test was of little value before the sixth week after the last normal menstrual period. However, after the second month, the latex test appeared quite reliable. The poor sensitivity of the latex test may be explained by the low concentration of chorionic gonadotropin during the early gestational period. Previous reports have stressed the importance of urine concentration. The tests in the present study were done with urine having a specific gravity of 1.015 or greater.

Both tests are simple procedures. The Friedman test requires 48 hours to complete and the latex test four hours. The major disadvantage to the Friedman test lies in the greater time involved and the care of the rabbits. The greater accuracy of the Friedman test outweighs this inconvenience. The Friedman test is more sensitive and specific for the determination of pregnancy than the in vitro immunologic test.

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